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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,199	10/10/2003	Peter Hermentin	06478.1495	1253

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,199	HERMENTIN ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 2, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 10, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to because Figs. 1, 3, 5 and 7-8 have poor resolution, which renders the gels and blots contained therein unreadable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specific claim rejections under 35 USC 112, second paragraph, set forth infra, may be considered relevant to other claims not explicitly mentioned, as deemed reasonably appropriate.

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In claim 16, the recitations of "the multimers", "multimer-forming therapeutic proteins", "the multimer bands", "the blotting membrane", and "the gel" lack antecedent bases. In addition, the recitation of "therapeutic" is indefinite because it is not clear who is being treated, what disease or disorder is being treated, or what agent(s) or method(s) is required for therapy. In addition, the recitation of "submarine" is indefinite because it is not clear what property or characteristic of gel electrophoresis is "submarine" or whether claim 1 requires a naval vessel (see e.g. specification p. 5, line 37, "catamaran") or a large hoagie-like sandwich (see e.g. specification p. 9, line 9, "blot sandwich"). In addition, the recitation of "suitable" is indefinite because "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of suitability required by "suitable" and a person of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In addition, the recitation of "chosen from" is indefinite because it is not clear whether a Markush-type claim is intended. In addition, the recitation of "an immunochemical method chosen from... a suitable dye in the gel" is indefinite because it is not clear how "a suitable dye in the gel" amounts to "an immunochemical method." In addition, it is not clear whether "multimer bands are visualized" simultaneously using a "blotting membrane" and a "dye in the gel", or whether the same gel is used for both blotting and dyeing, or what the exact purpose of dyeing a gel after blotting is. In addition, claim 16 is further indefinite for being incomplete or omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the step of "quantitative" determination of multimers. Claim 16 recites a method wherein multimer bands are "visualized immunochemically." It is not clear how the mere recitation of "visualized immunochemically" amounts to a "quantitative" determination of multimers.

In claims 21 and 23, it is not clear whether the recited agarose gels are the same gels used in parent claims, or whether the recited agarose gels are used in addition to previously recited agarose gels.

In claims 27-28, it is not clear why it is necessary or how it is possible to stain a gel after the gel has been blotted.

In claim 28, the recitation of "employed" is indefinite because it is not clear what object(s) is "employed." It is not clear whether the agarose gel is "employed", or whether the backing sheet is "employed," or whether both the agarose gel and the backing sheet are "employed." In addition, it is not clear how a backing sheet is "employed for the blue staining in the gel."

In claim 29, the recitation of "the agarose gel employed for immunostaining" lacks antecedent basis and is indefinite because it is not clear how an agarose gel is "employed" as a immunostain or whether the agarose gel or the blotting membrane, or both, are immunostained. In addition, the recitation of "chosen from" is indefinite because it is not clear whether a Markush-type claim is intended. In addition, the recitation of "the blotting process" lacks antecedent basis.

In claims 30-32, the recitation of "the bands" is indefinite because it is not clear what "bands" from claim 16 are referenced. It is not clear whether "the bands" references gel bands or blot bands, or both.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-27 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connaghan et al., 65 BLOOD 589 (1985), in view of Krizek & Rick, 97 THROMB. RES. 457 (2000).

Connaghan et al. teach the qualitative (see e.g. Fig. 1) and quantitative (see e.g. Fig. 2, "densitometric analysis") electrophoretic determination of von Willebrand factor and fibrinogen (see Fig. 1) using a

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continuous agarose gel (see p. 590, col. 2, *Gel Electrophoresis*) stained with a suitable dye (see p. 591, col. 1, "Coomassie Blue R-250").

Connaghan et al. do not perform Western analysis using a specific antibody-enzyme conjugate. However, Krizek & Rick teach a method for detecting von Willebrand factor by Western blot (see Abstract) using an antibody-horseradish peroxidase conjugate (see p. 459, col. 1, 1.7. *Immunolocalization of vWF Multimers*). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the determination of von Willebrand factor and fibrinogen of Connaghan et al. with the use of Western analysis because Krizek & Rick discovered several advantages to their method, including rapid processing, simplicity of gel preparation, high sensitivity to low concentrations of von Willebrand Factor, and elimination of radioactivity (see Abstract).

With respect to claims 20-25, Connaghan et al. teach a method wherein the agarose gel has 2% by weight agarose and the electrophoresis is carried out at 10 degrees Celsius (see p. 590, col. 2, *Gel Electrophoresis*).

With respect to claim 32, Krizek & Rick teach a method wherein the blot bands are quantified (see p. 459, col. 2, 1.9. *Densitometric Analysis*).

With respect to claim 33, Connaghan et al. teach a method wherein the gel is laminated (see p. 591, col. 1, "gel was then dried on a slab gel drier", *noting* that "slab gel drier" necessarily teaches a multi-layered gel laminate, e.g. including Whatmann filter paper, and would be so recognized by persons of ordinary skill in the art.)

With respect to claim 34, Krizek & Rick teach a method wherein the blot is laminated (see p. 459, col. 1, *Visualization of VWF Multimers*, "wrapped in plastic wrap").

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connaghan et al., 65 BLOOD 589 (1985), and Krizek & Rick, 97 THROMB. RES. 457 (2000) as applied to claims 16-17, and further in view of Riley & Provonchee (US 6,090,255).

Connaghan et al. and Krizek & Rick teach qualitative and quantitative electrophoretic determination of von Willebrand factor and fibrinogen as substantially described supra. The aforementioned references do not teach an agarose gel having a "backing sheet."

However, Riley & Provonchee teach a package (see Title) of agarose gels (see col. 2, lines 35-38) having support sheets (see e.g. Fig. 3, "support sheet 24", "spacers 26") for providing support to fragile agarose gels. Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method of Connaghan et al. and Krizek & Rick with the use of backing sheets because Riley & Provonchee discovered that backing sheets provides a rigid support for gels, which minimizes inadvertent bending and damage to gels during shipment and facilitates the removal of gels from the packaging (see col. 2, lines 7-43).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv



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1/24/05